dallen MEDICAL

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

GENERAL INFORMATION

APPLICANT: Dallen Medical, Inc.
1046 Calle Recodo, Suite G
San Clemente, CA 92673
(949) 218-0030
(949) 218-0040 Fax

JUL 25 2013

CONTACT PERSON: Al Memmolo
Chief Operating Officer

DATE PREPARED: June 6, 2013

DEVICE DESCRIPTION:

TRADE NAME: Compressyn™ Band

MODEL: 09-0002, 09-0005

GENERIC/COMMONNAME Cerclage Bone Fixation

CLASSIFICATION NAME: Bone Fixation, Cerclage, CFR 888.3010 (code JDQ)

DEVICE CLASSIFICATION: Class II

PREDICATE DEVICES: Compressyn™ Band (K101484)

Product Description:

The Compressyn™ Band System consists of a stainless steel coupler preloaded with a polymer coated polyester fiber band. It is a cerclage fixation device that is placed around or through the sternum and locked in place to provide stabilized fixation.

dallen MEDICAL

Indications for Use:

The Compressyn™ Band is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

Technical Characteristics:

The Compressyn™ Band has similar physical and technical characteristics to the predicate device.

Performance Data:

All necessary verification and validation testing has been performed with the Compressyn™ Band to assure substantial equivalence to the predicate device. Comparative testing in comparison to the predicate device included the following tests:

- Sternal compression
- Static performance
- Cyclic performance to 2000 cycles

The testing demonstrated that the Compressyn™ Band is substantially equivalent to the predicate device.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation, performance data, and overall technological characteristics, the Compressyn™ Band is determined to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 25, 2013

Dallen Medical, Incorporated
% Mr. Al Memmolo
Chief Operating Officer
1046 Calle Recodo, Suite G
San Clemente, California 92673

Re: K130431
Trade/Device Name: Compressyn™ Band
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Date: June 6, 2013
Received: June 7, 2013

Dear Mr. Memmolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130431

Device Name: **Compressyn™ Band**

Indications for Use:

The Compressyn™ Band is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices